

**EXHIBIT 22**

**to**

**Declaration of Kenneth A. Gallo in  
Support of Defendant's Motion for  
Reconsideration or, in the Alternative, for  
Certification of an Interlocutory Appeal**

## Joe Morrison

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**From:** Jon Ward <wardjp@ajwtech.com>  
**Sent:** Friday, May 10, 2013 3:58 PM  
**To:** Joe Morrison; Lauren Chrapowitzky; Jon Werner; Jeff Bua  
**Subject:** DaVinci Project Overview

Joe,

Please find the below summary of how we are viewing our role(s) in the Da Vinci Project as we understand them.

1. AJW Technology Consultants, Inc. Team, consisting of Jon Ward, Jon Werner, Lauren Chrapowitzky (others as needed), will support Benjamin Biomedical and a new entity in developing the following documentation:
  - a. Testing plans - (Jon Werner and Jon Ward)
    - i. Board Level (preliminary)
      1. EMI / RFI
      2. Sterilization
      3. ROHS
      4. Vibration
      5. Drop
      6. Handling
      7. Sealing for immersion
    - ii. Endowrist level (Preliminary)
      1. Electrical Safety/interference
      2. Life testing
      3. Biological evaluation
      4. Software
      5. Cleaning
      6. Sterilization
  - b. Design History File [with the intent to have the data support a potential 510(k) submission] – (Jon Werner and Jon Ward)
    - i. Will probably utilize the format Pete has prepared for the existing repairs.
  - c. Quality system / process development (Lauren Chrapowitzky and Jon Ward)
    - i. This may include an overview of the processes, mapping etc to determine the necessary validations
    - ii. May include template procedures to be updated per the actual process

We understand that prototypes may be available sometime in June for testing, as such test plans are the first priority, specifically at the board level; followed closely by testing plans at the endowrist level.

Items we are waiting for to really get started:

1. Instruction manuals for the endowrists,
2. Testing plans for the board with interceptor chip (preliminary list has been provided)
3. Timelines for expected completion of tasks

Best regards,

Plan

- Cell Rte 11:00 -

- Grouping for Apples Testing

- review drawings sent + air group

- Process materials

- Room due 16th

@ 16th Jan; 16-20th

- tensor wrench adapt

- Ken Spu

- ~~Ken~~ Ken Spu

- mega needle driver <sup>drawn</sup> → e tool end

Blue stuff ! !

not green

## PROJECT OBJECTIVE

Establish method for servicing robotic surgical EndoWrists ("Wrists") originally manufactured by Intuitive Surgical and utilized as an accessory in Intuitive's DaVinci robotic surgical system ("Host System"). The objective is to offer users a serviced Wrist as an alternative to purchase of a replacement new OEM Wrist.

Service shall mean to inspect, clean, repair and test the Wrist so that:

1. The Wrist's useful life is re-set and extended.
2. The Wrist's functionality and safety are equivalent to OEM Wrists.
3. The Wrist is 100% compatible with the Host System.

## DEVICE DESCRIPTION

Wrists are robotic surgical instruments used as accessories in the DaVinci robotic surgical system. Wrists are class \_\_\_\_ devices. Wrists currently consist of (# of models) models grouped into (\*\*number of classifications) based upon: Generation of Host System (Gen1. Or Gen 2.), the tool head (various models of forceps, blades, scissors, grippers and other misc), and whether the Wrist is an electrically powered cautery model or standard, non-electrical model.

Electrical Wrist are either monopolar, bipolar or PK powered models. In addition to connecting to the Host System, electrical Wrists are also connected to an electro surgical power system. There are (\*\* number) of potential electrical power systems that can be used with the Wrists .

The Wrist tool heads are the patient contact portion of the Host System.

As marketed by the OEM each Wrist has a specific, limited useful life measured by the number of uses on the Host System. Upon each use, software on a PCB in the Wrist decreases the available useful life by one use. Upon hitting zero uses remaining, the software automatically causes the Wrists to become completely non-functional ("expire"). The use count expiration is automatic and occurs with each Wrist regardless of whether or not there is any other fault condition.

Currently, users have no alternative but to discard an expired Wrist and purchase a new replacement Wrist from the OEM.

## REGULATORY CLASSIFICATION:

FDA: Serviced Wrists will be considered "remanufactured" devices for FDA purposes because the serviced Wrists will have a useful life beyond that established by the OEM. As a result this project will require FDA registration, 510 (k) submission, and full compliance with 820 quality system requirements including Design controls.

ISO: For international marketing the Serviced Wrists will require CE marking and therefore full compliance with both 13485 Quality System and 14971 Risk Management requirements and creation of a Technical File .for product planning / design.

SUMMARY OF PLANNED SERVICE:

Service will consist of 1). extending and re-setting the useful life of the Wrist, and 2). inspecting, cleaning, adjusting the cable tension, replacing or repairing worn/damaged parts, and testing, to confirm the Wrist is operating within the safety and functional specifications of the OEM and is fully compatible with the Host System.

1. Extending Useful Life. The useful life will be extended by replacing the OEM PCB with one designed and developed for the Serviced Wrist ("New PCB"). The DS2505 chip from the OEM PCB will be harvested and attached to the New PCB. The New PCB will include an interceptor chip ("Chip") with software to re-set the useful life of the Wrist and change the serial number if necessary. The New PCB will be programmed twice as part of the assembly process, once pre- DS2505 attachment and once post-attachment. In order to extend life, an OEM Wrist must have at least one remaining use left. Expired OEM units cannot be re-set. A Serviced Wrist can be re-set/extended after it is expired.

2. Functionality and Safety OEM Equivalence: The remainder of the servicing process will be to confirm that the Wrist is operating safely and functionally as originally manufactured by the OEM. This will be accomplished by a combination of characterization of OEM units, life testing, and third party testing. Whenever possible original unit components will be re-used, or alternatively, replaced with components salvaged from other OEM units. Where necessary, worn or damaged components will be replaced with new parts that are functionally equivalent to OEM.

Functionality is established by,

- \*Machine (Host System) recognition
- \*Cable tension
- \*Range of Motion
- \*Tool head Cutting and Gripping (as applicable)
- \*Physical Integrity of Wrist
- \*Electrical Performance??

Safety is established by

- \*Electrical Testing
- \*Sterilization and Cleaning Process
- \*Life Testing
- \*Replacement Part Design Specifications

-OEM Characterization:

- \*Tension
- \*Range of Motion
- \*Cutting and Gripping

-Life Testing:

\*Unit integrity, functionality, and safety will all be confirmed via a life testing protocol that will include repeated use, sterilization and cleaning cycles per OEM specification. The protocol will include testing at stated intervals and at the completion to establish that the Wrist functions safely and effectively throughout the extended useful life.

-3<sup>rd</sup> Party Testing:

- \*Electrical (Horizon, RMS, Test House: SGS)
- \*EMC (Horizon, RMS, Test House: SGS)
- \*Sterility (RMS, Test House: \*\*)
- \*Biocompatibility (RMS, Test House: \*\*)

When salvaging components and confirming via life testing it is important to inspect for wear, corrosion from autoclave, fraying of cable, and any other signs of damage.

DESIGN & DEVELOPMENT OUTLINE:

D&D will be performed and documented per the applicable FDA design control requirements and the design / product planning requirements of ISO 13485 and 14971 Risk Management.

The company has established procedures to implement Design.

See Design Plan for preliminary schedule of action items, deliverables, responsibility and initial schedule.

Identification of Regulatory Requirements

-See RMS E-mail (Jon Werner dated \*\*\*)

Identification of Testing Requirements:

Special Functions:

- Soldering Certifications
- PCB Handling / ESD procedures

Installations / Validations:

- PCB Software Validation package (G-5, RMS)
- New PCB Programming / Production Release (G-5, RMS)
- Programming Fixture (G-5, RMS)
- Autoclave (RMS)
- US Cleaner (RMS)
- Tension Fixture (Casica)
- Range of Motion Fixture (Casica)
- Electrical? (Horizon)
- Other?